White Paper on CTMS

Accelerate Your Clinical Trial Data Management with ReliSource's Customized CTMS Solution



Introduction:

With the importance of healthcare and telemedicine soaring worldwide, the clinical trial is being reimagined. Stakeholders now rely on Clinical Trial Management System software to a great extent to assess information for clinical study and make decisions. Given the global unrest conditions in the fields of detection, diagnosis, and assessment of health data to achieve an appropriate and expected outcome from a physical test, CTMS helps in such cases with enormous possibility and accuracy to collate the clinical data for study and consent patients by ensuring compliance when the patients and doctors are even at the remote positions [1].

ReliSource in CTMS Development:

We, <u>ReliSource</u> has a decade long experience in working with leading CRO companies across the world offering high performing, customized and effective CTMS development.

We have an enriched experience in providing service to leading healthcare industries and have been developing comprehensive CTMS platforms to aid in clinical trial data & workflow management that expedites the need of ReliSource in the development and expansion of business.

The fields where the benefits of working with ReliSource be highly encouraging can be categorized into the following types: Product Development & Training, BI Reporting, Analytics & Machine Learning and mHealth & ePro Solutions.

We expedite and extends our CTMS development service in the followings areas:

- eSource platform for eCOA, i.e., PRO, PerfO, ClinRo, ObsRo.
- **EDC** to capture data.
- eConsent for the automated informed consent process.
- LMS to administer, track and report on physicians' training, etc.

Our Value Adds:

With extensive experience in operational support, study start-up, site validation, project management in clinical trials & research space ReliSource ensures the following advantages:

- Improved clinical trial management
- Better trial and site planning
- Tracking of Site and Subjects across all studies
- Streamlined PI and Investigator management which allows sponsors to manage relationships with investigators, based on visibility into the status study
- Reporting/dashboards to communicate trial performance against targets, as well as other operational reports
- Ensures accessibility to accurate and up-to-date study information with the aid of the CTMS solution that provides transparency and unified access to assess data to help make sound decisions.
- *Collaboration:* ReliSource can collaborate with cross-functional teams such as Sponsors, CROs and Technology Partners, on an assigned project or task using the CTMS platform to achieve an effective and timely outcome.
- *Efficiency:* The CTMS productivity tool helps ReliSource and their clients to plan, track and monitor the professional undertaking more effectively and conveniently.
- *Oversight:* ReliSource provides transparency to inspect and observe the critical components of a clinical study assessment, using their decade-long domain knowledge on CTMS platform development.





Fig.1. CTMS Scopes

Use Cases:

ReliSource has been an integral part of some of the Fortune 500 companies in delivering high quality and optimized CTMS platform development for smooth e-clinical trial based operations. The development in CTMS platform to aid in clinical trial data management encompasses the following wide range of accomplishments [1]:

> eData Transfer:

ReliSource has successfully completed the electronic data transfer for its clients. Developed and deployed EDC tools to capture patient data both on-site and remote.

Process Improvement:

Analyzed some of the existing processes that were followed and proposed some improvements

> ePRO App:

ReliSource, in conjunction with the partners and CROs, developed the ePRO Mobile App and validated it in accordance with FDA regulations 21 CFR Part 11.

> BI Reporting:

Gathered core knowledge of clients' business & hands-on experience on clients' legacy systems. Defined a complete ecosystem of data warehouse utilizing ETL and BI Reporting tools. Designed perfect data loading strategy to ensure real-time & precise business reporting.

LMS/e Learning:

ReliSource supported and maintenance for LMS/eLearning applications by developing LMS platforms to administer, track and



report on the training of physicians by acquiring full knowledge of LMS tasks in the quickest possible time and independently handling the entire development process. Semi-automation script for new RPE development ensuring faster, error and risk-free process was developed. Also,

updated automation script of Pulling score for easier execution.

➢ eCOA:

ReliSource developed the eSource platform for clinical outcome assessments (eCOA).

The following figure 2 illustrating the core accomplishments by ReliSource on CTMS platform provides a glimpse of the expertise and cutting-edge experience of us which helped gain the trust of our potential clients and partners around the world to collaborate with us in carrying out projects on clinical trial management.

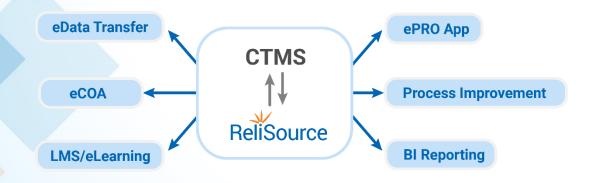


Fig.2. The block diagram depicting the services and products offered by ReliSource acquiring CTMS

Conclusion:

After the completion of a successful CTMS project, you will be able to discover the immediate advantages:

- Improved ROI and revenue
- Platform's usability optimization
- Improved analytics
- Improved clinical trial management
- Better trial and site planning
- Tracking of site and subjects across all studies, etc.

References:

- 1. Internal presentation on Healthcare Industry Expertise of ReliSource, 2021.
- 2. Simple Trials, "CTMS", April 2021. Available at: <u>https://www.simpletrials.com/what-is-a-ctms</u>

